

ADVANCED HONEY LEMON COUGH DROPS- cough drops lozenge
ADVANCED FIRST AID, INC.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active Ingredient (in each lozenge) - Menthol 8.6mg

Cough suppressant / Oral Anesthetic

Uses: temporarily relieves • cough as may occur with a cold • occasional minor irritation and sore throat

Warnings:

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. These symptoms may be serious.

Ask a doctor before use if you have: • persistent or chronic cough such as occurs with smoking, asthma, or emphysema

• cough accompanied by excessive phlegm (mucus)

Stop use and consult a doctor if:

• cough persists for more than 7 days, tends to recur, or is accompanied by fever, rash or persistent headache. These could be signs of a serious condition.

• sore throat is severe, or irritation, pain or redness lasts or worsens

• sore mouth does not improve in 7 days

If pregnant or breast-feeding baby, ask a health professional before use.

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions:

• **Adults and children 5 years and older:** Allow lozenge to dissolve slowly in mouth; may be repeated every hour as necessary or as directed by a doctor.

• **Children under 5 years:** Consult a doctor.

corn syrup, eucalyptus oil, D&C Yellow #10, FD& C Yellow #6, honey, lemon oil, sucrose

Product #1214

100 Drops

Menthol - Cough Suppressant/Oral Anesthetic
Pastillas para la Tos con sabor a miel y limón

**Honey Lemon
Cough Drops**

Product #1214

100 Drops

DRUG FACTS

Active Ingredient (in each lozenge) Purpose
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Directions:
- Adults and children 5 years and older: Allow lozenge to dissolve slowly in mouth; may be repeated every hour as necessary or as directed by a doctor.
- Children 5 years and under: Consult a doctor.

Other information:
- 15 calories per drop
- Store at controlled room temperature 15° to 30°C (59° to 86°F)
- Protect from moisture and heat

Inactive Ingredients: corn syrup, eucalyptus oil, D&C yellow #10, FD&C yellow #6, honey, lemon oil, sucrose

Manufactured For:
Advanced First Aid, Baltimore, MD 21237
www.advanced1staid.com • 1-888-922-5878

MADE IN THE USA

Honey Lemon
Cough Drops

Menthol - Cough Suppressant/Oral Anesthetic
Pastillas para la Tos con sabor a miel y limón

PULL TO OPEN

100 Drops

Do not use if individual packet is open or torn.

Honey Lemon
Cough Drops

Menthol - Cough Suppressant
Oral Anesthetic

- Temporarily relieves minor sore throat and cough
- Pleasant tasting formula
- Menthol eucalyptus vapors ease congestion

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ADVANCED HONEY LEMON COUGH DROPS

cough drops lozenge

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67060-121
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	8.6

Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	
CORN SYRUP (UNII: 9G5L16BK6N)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HONEY (UNII: Y9H1V576FH)	
LEMON OIL (UNII: I9GRO824LL)	

Product Characteristics

Color	yellow (BRIGHT YELLOW)	Score	no score
Shape	OVAL	Size	23mm
Flavor	MENTHOL	Imprint Code	P
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67060-121-74	100 in 1 CARTON	08/07/2019	
1	NDC:67060-121-01	1 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/07/2019	

Labeler - ADVANCED FIRST AID, INC. (114477180)**Registrant** - ADVANCED FIRST AID, INC. (114477180)**Establishment**

Name	Address	ID/FEI	Business Operations
ULTRA SEAL CORPORATION		085752004	pack(67060-121)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmaloz Manufacturing, Inc.		067101998	manufacture(67060-121)

